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Comparison Costs of ERCP and MRCP in Patients with Suspected Biliary Obstruction Based on a Randomized Trial

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ABSTRACT

Background: The optimal management of patients with suspected biliary obstruction remains unclear, and includes the possible performance of magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde cholangiopancreatography (ERCP). **Objectives:** To complete a cost analysis based on a medical effectiveness randomized trial comparing an ERCP-first approach with an MRCP-first approach in patients with suspected bile duct obstruction. **Methods:** The management strategies were based on a medical effectiveness trial of 257 patients over a 12-month follow-up period. Direct and indirect costs were included, adopting a societal perspective. The cost values are expressed in 2012 Canadian dollars. **Results:** Total per-patient direct costs were Can$3547 for ERCP-first patients and Can$4013 for MRCP-first patients. Corresponding indirect costs were Can$732 and Can$694, respectively. Causes for differences in direct costs included a more frequent second procedure and a greater mean number of hospital days over the year in patients of the MRCP-first group. In contrast, it is the ERCP-first patients whose indirect costs were greater, principally due to more time away from activities of daily living. Choosing an ERCP-first strategy rather than an MRCP-first strategy saved on average Can$428 per patient over the 12-month follow-up duration; however, there existed a large amount of overlap when varying total cost estimates across a sensitivity analysis range based on observed resources utilization. **Conclusions:** This cost analysis suggests only a small difference in total costs, favoring the ERCP-first group, and is principally attributable to procedures and hospitalizations with little impact from indirect cost measurements.

Keywords: biliary obstruction, costs, ERCP, MRCP.

Introduction

The optimal management of patients with a moderate likelihood of biliary obstruction after initial laboratory tests and imaging with ultrasound remains unclear, especially in the presence of many noninvasive imaging options, including magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde cholangiopancreatography (ERCP) [1–3]. In addition to malignancies such as pancreatic cancer [4], which carry a significant burden of illness, most of the societal costs are probably related to one of the most frequent causes of biliary obstruction in a general medical practice: common bile duct stones or choledocholithiasis. Indeed, gallstone disease (gallbladder, including 10% of these patients who carry common bile duct stones [1,3,5–7]) is responsible for about 1.8 million ambulatory care visits and more than 700,000 cholecystectomies yearly in the United States [1,8,9]. Gallstone disease is the second most common reason for hospital admissions (with an estimated cost of US $5.8 billion annually), although only 15% of the people with gallstones have related symptoms [1,3,5–7]. The initial management strategy needs to consider the diagnostic yield of these technologies and weigh the benefits with the small but significant complications attributable to ERCP, which, however, can also provide therapy.

We completed a medical effectiveness randomized trial comparing an ERCP-first approach with an MRCP-first approach in patients with suspected bile duct obstruction after an initial clinical evaluation and ultrasound examination, in whom a further workup was needed to establish a diagnosis. The following cost analysis is based on original utilization data collected as part of the trial.

Methods

The Randomized Clinical Source Trial

This cost analysis is based on a recently published randomized controlled trial (RCT) [10] comparing ERCP with MRCP in the

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management of patients at moderate likelihood of a suspected biliary obstruction.

The RCT comparing MRCP with ERCP provided information about the main medical resources of all 257 included patients and time lost related to the suspected biliary obstruction with its assessment and management. We calculated the observed direct costs resulting from the observed medical visits, ERCP and MRCP procedures, and hospitalizations. Indirect costs were also tabulated on the basis of observed time lost because of the medical condition.

In the randomized trial, the patients were randomized to an ERCP-first strategy or an MRCP-first strategy, stratified by the level of obstruction. The primary outcome was the occurrence of a disease- or procedure-related biliopancreatic adverse event within the next 12 months. Secondary outcomes were the number of subsequent biliopancreatic procedures, the duration of hospitalization, days away from activities of daily living (ADL), and mortality. In this trial, a strategy of MRCP-first decreased the need for subsequent MRCPs but not complications. The source RCT was conducted at the McGill University Health Centre and the Sir Mortimer B. Davis – Jewish General hospital, two tertiary care centers in Montreal (Canada). All patients older than 18 years with suspected biliary obstruction over a 4-year period were considered for recruitment if they were referred for a noninvasive radiological investigation (ultrasound or computed tomography scan of the abdomen) showing a dilated common bile duct or directly for an ERCP or MRCP. The patients were openly allocated to one of the two study groups and followed for 12 months [10]. A scheduled follow-up visit was planned every 3 months. Only pertinent durations of hospitalization were measured, as defined by any hospitalization because of the workup or treatment of the biliopancreatic condition, or any adverse event thereof as determined by an ad hoc expert panel.

The trial was recently published [10] and, in brief, 126 patients were randomized to an ERCP-first and 131 to an MRCP-first strategy (both groups exhibiting similar characteristics, age 54 ± 18 years, 62% women, 39% postcholecystectomy). In follow-up, 18 (14.3%) ERCP-first and 25 (19.1%) MRCP-first patients experienced a procedure- or disease-related complication ($P = 0.30$). A cause of biliary obstruction was found in 39.7% versus 49.6% of the patients ($P = 0.11$). Sixty-six (50%) patients in the MRCP-first group ended up avoiding an ERCP in follow-up. Overall, 20 (7.8%) patients died during the study period, with no significant difference between the two groups (7.9% for ERCP and 7.7% for MRCP; P = NS) and no procedure-related mortality.

General Considerations as to the Determination of Costs

We associated a cost to each of the resources used by both randomized groups of patients as collected in follow-up. Direct and indirect costs were included. We performed our cost analysis assuming that all other factors remained the same outside disease- or procedure-related resources, especially because we only collected disease-related resource utilization as described above. In other words, we assumed that there were no differences in transportation costs, in personal consumption of pharmaceutical drugs, or in utilization of medical care services other than for the RCT-related medical conditions in both groups. All procedures, physician visits, lengths of stay, and disease-related complications were recorded in the RCT. Enrolled patients also received a questionnaire quantifying the time spent away from their usual activities because of the ERCP/MRCP procedure. A societal perspective was adopted [11,12].

For each strategy (ERCP-first and MRCP-first), a total direct average cost per patient was computed according to the study group, including the costs of the visits, as well as ERCP and MRCP procedures (initial and additional) with the corresponding physician fees (consultation costs were included in ERCP/MRCP procedures), and all days of hospitalization.

We present the mean quantity of individual resource utilizations by study group (Table 2), the time lost per patient (Table 3), and calculated the corresponding average direct and indirect costs at the patient level with lower and upper quartile estimates (Table 4). All cost results cover a 12-month study horizon paralleling the RCT study design. The cost values presented in this analysis are expressed in 2012 Canadian dollars (Can$).

Determination of Direct Costs

Hospitalization Costs

Direct hospitalization costs were derived from the Canadian Institute for Health Information (CIHI) [13] (Table 1). CIHI is a Canadian organization that provides national estimates of medical resources on the basis of a relative resource allocation methodology for estimating a hospital's inpatient cost. More precisely, this organization computes a resource intensity weight per homogeneous case-mix group of diagnoses (CMG) based on *International Classification of Diseases, Tenth Revision* diagnostic codes. This resource intensity weight per CMG (that includes all institutional costs with overhead costs but without physician fees) is then multiplied by a unique average cost per weighted case to give a final hospitalization cost per CMG. Using the CIHI estimations, we therefore computed a per diem cost associated

Table 1 – Unit costs.

Cost item	Cost value*	Source
Visit (gastroenterology)	25	RAMQ [19]
Consultation (gastroenterology)	150	RAMQ [19]
Total cost for an ERCP procedure (diagnosis) as initial procedure	1449	RAMQ [19]; CIHI [13]
Total cost for an ERCP procedure (therapeutic) as initial procedure	1539	RAMQ [19]; CIHI [13]
Total cost for an ERCP procedure (diagnosis) as secondary procedure	1324	RAMQ [19]; CIHI [13]
Total cost for an ERCP procedure (therapeutic) as secondary procedure	1414	RAMQ [19]; CIHI [13]
Total cost for an MRCP procedure	1270	RAMQ [19]; CIHI [13]
Hospitalization for pancreatitis	4878	CIHI [13]
Hospitalization for gatrointestinal hemorrhage	3677	CIHI [13]
Hospitalization for peforation	7001	CIHI [13]
Hospitalization for cholangitis	4224	CIHI [13]
Hospitalization for cholecystectomy	4401	CIHI [13]
Average per diem cost for hospitalizations due to complications in suspected biliary obstruction	911	CIHI [13]
Time lost (1 d)†	127	Statistics Canada [21]

Note. Values were rounded to the nearest integer.
CIHI, Canadian Institute for Health Information; ERCP, endoscopic retrograde cholangiopancreatography; MRCP, magnetic resonance cholangiopancreatography; RAMQ, Régie de l'Assurance Maladie du Québec.
* All costs are expressed in 2012 Canadian dollars.
† Blended average cost that could vary according to age and sex group of the patient.

with what we defined as a complication-related hospitalization for our patient population. This computed per diem cost was the average cost of an adult admission registered for one of five selected CMGs—277 (pancreatitis), 254 (gastrointestinal hemorrhage), 251 (perforation), 278 (cholecystectomy), and 288 (cholangitis)—that represent the most commonly related complications for the condition of suspected biliary obstruction with an impact on hospitalizations or costs [14–18]. Patients who die during the hospitalization are excluded from cost estimates by the CIHI.

Physician Fees

The physician fees were derived from the single-payer provincial government, the Régie de l'Assurance Maladie du Québec [19].

Procedural Costs

We also estimated direct costs for MRCP and separate direct costs for a diagnostic or a therapeutic ERCP, depending on whether they were an initial or additional ERCP in the patient's management. In each comparison group, the percentages of diagnostic and therapeutic ERCPs were obtained from results of the source RCT [10]. These were 67.5% and 32.5% for the diagnostic and therapeutic initial ERCP procedures, respectively. Corresponding percentages for subsequent ERCPs were 44.4% and 55.6%. Among patients randomized to an MRCP-first strategy, 16.7% underwent a subsequent ERCP for sole diagnostic purposes; all others were therapeutic ERCPs. The total direct costs of each procedure were tabulated as the sums of the institutional fees and all professional fees related to the performance of ERCP or MRCP. For initial ERCP procedures, we assumed that a consultation in gastroenterology was required, versus only a visit for subsequent ERCPs. Estimates of institutional costs for ERCP and MRCP procedures were derived from the CIHI [13].

Determination of Indirect Costs

According to the human capital approach [11,20], indirect cost as an opportunity cost was based on the loss of productivity, that is, the time lost because of the condition of suspected biliary obstruction. This time was tabulated as the sum of the lengths of stays due to the hospitalizations, the time required for ERCP/MRCP initial and follow-up procedures, the time used for the medical visits, and any time lost in the patient's ADL. All times away from ADL were obtained from the trial's patient questionnaires unless specified above. The value of a patient's time was based on the hourly wages provided by Statistics Canada [21]. For the time spent away from usual activities, a specific hourly value was applied according to the age and sex of the respondents to the questionnaire. For the length of stay and the time spent to undergo ERCP and MRCP, a uniform average hourly wage for all the patients was used. We assumed that a patient spent 1 day to undergo an ERCP and a half-day for an MRCP or a visit in gastroenterology. The unit costs are presented in Table 1.

Sensitivity Analyses

We performed sensitivity analyses varying the clinically relevant outcomes across a meaningful range of possibilities (i.e., the lower and upper quartiles of units used of this resource multiplied by the unit resource cost) as informed by the RCT results.

Results

Direct Costs

Data for the use of medical resources are presented in Table 2. Average costs attributable to visits were similar in both groups. The MRCP-first group required a second procedure more often and exhibited more days of hospitalization than did the ERCP-first group. Table 4 provides the average direct costs per patient (with lower and upper bounds) generated by the medical resource utilization presented in Table 2. Procedures and hospitalizations (representing 99% of all direct costs) are the two resources that account for most of the Can$428 in additional total costs attributable to the MRCP-first group in comparison with the ERCP-first group.

Indirect Costs

Table 3 details the estimation of the time lost by patients because of their condition. In terms of time lost, all four categories of indirect costs (visits, procedures, hospitalization, and time away from ADL) contributed significantly to the overall indirect cost burden. Table 3 demonstrates that it is the ERCP-first patients who lose more time away from ADL. The corresponding cost values are presented in Table 4, demonstrating that the biggest difference in indirect costs stems from time away from ADL.

Absolute per-patient cost values are shown in Figure 1. On average, the management of a patient with suspected biliary obstruction costs Can$4279 using an ERCP-first approach versus Can$4707 when adopting an MRCP-first approach. In other words, choosing an ERCP-first strategy rather than a MRCP-first strategy would save on average Can$428 per patient in follow-up, based on the data gathered from the source RCT.

Table 2 – Medical resources utilization (per patient).

Medical item	Mean per patient in the ERCP-first group	Mean per patient in the MRCP-first group
Number of patients	126	131
Total number of visits (gastroenterology)	1.7	1.76
Initial procedure (ERCP and MRCP for each group)	1	1
Number of additional procedures (MRCP and ERCP)	0.29	0.56
Number of all ERCP-MRCP procedures	1.29	1.56
Total number of days of hospitalization*	1.81	2.11

Note. Values were rounded to the nearest two decimals.
ERCP, endoscopic retrograde cholangiopancreatography; MRCP, magnetic resonance cholangiopancreatography.
* Sum of all the days of hospitalization for all patients/number of patients. The average of the mean duration of stay per patient was 4.1 d for ERCP-first versus 4.6 d for MRCP-first. Difference in both formulas arises because some patients had more than one hospitalization.

Table 3 – Time lost (in days, per patient).

Time category	Mean per patient in the ERCP-first group	Mean per patient in the MRCP-first group
Number of patients	126	131
Total time spent for visits in gastroenterology	0.85	0.88
Total time spent to undergo ERCP or MRCP	1.21	1.03
Total time spent at hospital	1.81	2.11
Total of additional time spent away from ADL*	1.96	1.55

Note. Values were rounded to the nearest two decimals.
ADL, activities of daily living; ERCP, endoscopic retrograde cholangiopancreatography; MRCP, magnetic resonance cholangiopancreatography.
* Sum of all the days spent away from ADL for all patients/number of patients. The average of the mean duration of stay per patient was 3.4 d for ERCP-first versus 2 d for MRCP-first. Difference in both formulas arise because patients had variable numbers of events causing days away from ADL.

Discussion

ERCP and MRCP are among the most commonly performed procedures to investigate suspected biliary obstruction [1]. There exists equipoise as to which may be the best approach. This uncertainty lies in the realization that ERCP carries more risks, yet also offers the possibility of performing therapy at the same procedural setting. We recently published the final results of an RCT comparing an ERCP-first approach with an MRCP-first approach in patients with suspected lower bile duct obstruction [10], concluding that an MRCP-first strategy decreased the need for subsequent MRCPs but did not alter a priori–defined biliopancreatic or procedure-related adverse events, which was the most relevant single clinical outcome and was the primary outcome of the trial. We now compared the cost information collected as part of that trial, in the hope of better characterizing the two strategies.

After quantifying the direct costs of all medical resources used, we also estimated the indirect costs resulting from time lost because of the medical condition and its related diagnosis and treatment, although we did not capture transportation or caregivers' time-related costs. Total costs added up to Can$4279 per patient in the ERCP-first strategy and Can$4707 per patient in the MRCP-first strategy, for a difference of Can$428.

Although the ERCP-first patients lose more time away from ADL, there is a greater cost attributable to increased procedures and more days of hospitalizations noted in the MRCP-first patients. It is thus mainly the direct costs that account for the difference between each strategy over a 12-month period. A review of upper and lower quartile variations, however, shows great overlap between per-patient cost estimates in both groups. Many interpretations are possible. Because the savings represent about 10% of the total per-patient costs associated with either approach, the mean difference may be a valid unbiased (albeit uncertain) estimate, in which case the ERCP-first strategy could be favored as slightly more economically viable. Alternately, the mean difference of Can$428 in cost could be interpreted as unimportant given variability in the costs, and the procedures could be considered equivalent. However, we feel that the most conservative and likely interpretation (especially in light of the difference in clinical procedural risks) is that the analysis is inconclusive because the trial was too small and the uncertainty over the cost difference resultantly too big.

These findings were somewhat surprising because the MRCP diagnostic test is touted to be less invasive than the ERCP alternative, which bears significantly greater risks. This observation is likely explained by the number of MRCP-first patients who subsequently underwent an ERCP (66 of 131) (probably because of persistent diagnostic uncertainty resolved by the performance of the more invasive diagnostic approach), as well as the downstream hospitalizations noted in the MRCP-first group (this latter difference may have been related to chance alone because there are no biological explanations for this finding). The actual difference in procedure institutional unit costs between ERCP and MRCP is minimal (Table 1) [13]. There exist, however, differences in physician fees for each procedure, especially with regard to the performance of a therapeutic ERCP in keeping with provincial reimbursement schedules [19].

A number of methodological and clinical issues are worth mentioning. The data, particularly the probabilities and efficacy information, were drawn directly from the RCT findings. Because these data are a result of direct clinical observation and not theoretical assumptions, their clinical relevance is obviously heightened; indeed the medical resources recorded did not stem from a retrospective gathering of self-report questionnaires but rather from actual medical management information as determined by prospective data collection by research nurses in a standardized fashion. Although more generalizable because the study was designed as a medical effectiveness trial, the data may still be limited in their external validity, especially because the RCT was carried out only in two hospitals, on three sites; the selection of patients was also more explicit and systematized than may be the case in general practice. This randomized trial, however, is the only such evaluation having been completed in the literature that attempts to measure the true downstream clinical impact of an ERCP-first strategy versus an MRCP-first strategy in diagnosing and then treating patients with a moderate likelihood of biliary obstruction (stricture or stone). Such evaluative attempts, in general, are few because the intervention (diagnostic) may occur far upstream in the clinical pathway of a given patient, when compared with the final clinical outcome. A recent RCT suggested a lesser complication burden when performing an endoscopic ultrasonography–first compared with an ERCP-first approach [22]. Although the approach to patients with biliary obstruction emphasizes a noninvasive paradigm, the general principles of the clinical paths adopted in the trial and the technologies of ERCP and MRCP used then are very much similar to those used today, both in Canada and in other Western and Asian countries. Local practices with access to endoscopic ultrasonography expertise and equipment may alter the choice of noninvasive imaging, yet in many centers, endoscopic ultrasonography resources, such as in our own, are mainly taken up by indications for malignant diseases, including extrabiliary organs such as esophagus, stomach, duodenum, rectum, and lung.

Table 4 – Total direct and indirect costs*.

Cost center	ERCP-first group				MRCP-first group			
	Average cost per patient	Proportion of total direct/ indirect costs (%)	Lower bound	Upper bound	Average cost per patient	Proportion of total direct/ indirect costs (%)	Lower bound	Upper bound
Direct costs								
Gastroenterology visits	42	1	25	100	44	1	37	125
Procedure ERCP/MRCP	1856	52	1443	2888	2043	51	1303	2608
Hospitalizations	1648	46	911	4100	1926	48	911	4255
Total direct costs	3547	100	2379	7088	4013	100	2251	6988
Indirect costs								
Time spent on gastroenterology visits	108	15	63	255	112	16	95	318
Time spent on ERCP/ MRCP procedures	154	21	119	241	131	19	122	170
Time spent at hospital	230	31	100	358	269	39	96	438
Time spent away from ADL	239	33	0	652	183	26	0	439
Total indirect costs	732	100	282	1506	694	100	313	1365
Total direct and indirect costs	4279		2661	8594	4707		2564	8353

Note. Values were rounded to the nearest integer. Low and high values are based on the lower (25%) and upper (75%) quartiles.

ADL, activities of daily living; ERCP; endoscopic retrograde cholangiopancreatography; MRCP, magnetic resonance cholangiopancreatography.

* All costs are expressed in 2012 Canadian dollars.

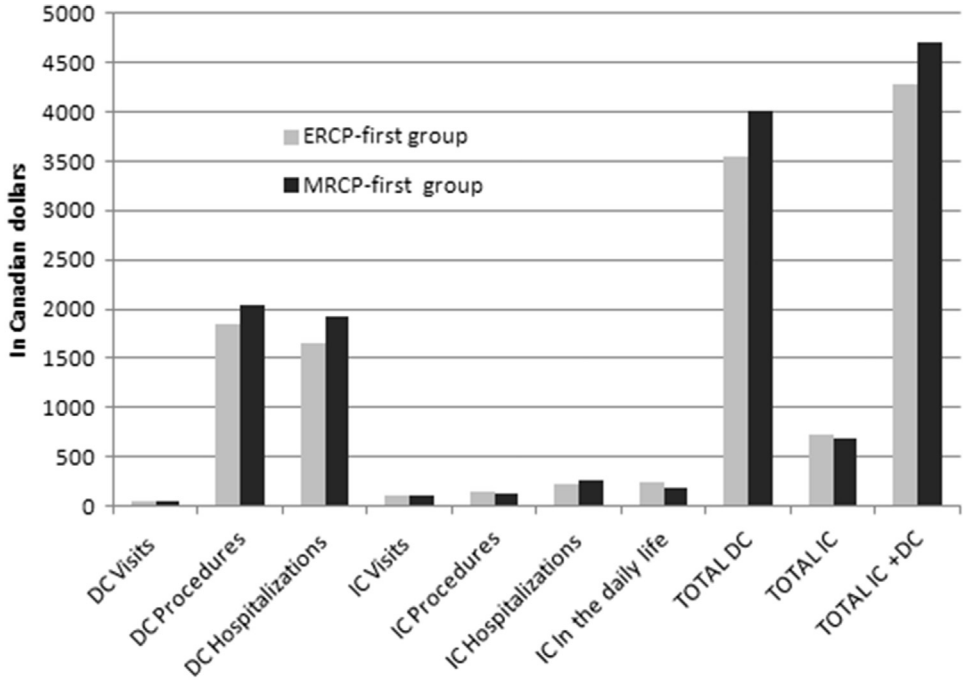

Fig. 1 – Per-patient costs.
Period of time: 12 months.
ERCP, endoscopic retrograde cholangiopancreatography; MRCP, magnetic resonance cholangiopancreatography; DC, direct costs; IC, indirect costs.

The methodology adopted for the determination of costs also warrants discussion. We adopted a societal perspective as recommended [11,12,23–26]. The unit direct costs were based mainly on representative national averages. Only a limited number of physician fees were province-specific for Quebec [19], and these latter costs represent just a small part of the total direct costs. We included all follow-up resources noted by the research nurses, but here too are once again limited by the information available from the RCT [10]. The five diagnoses identified for the calculation of the per diem in this analysis (pancreatitis, gastrointestinal hemorrhage, perforation, cholecystectomy, and cholangitis) represent the most common complications encountered, both related to procedures (ERCP) and the natural history of the conditions most frequently found to be the cause of lower biliary obstruction (gallstones with or without choledocholitiasis, and more rarely in a general practice, pancreatic cancer). The choice of time horizon is adapted to the clinical context as detailed in the randomized trial protocol and publication, and was limited by the follow-up in our RCT. Either a longer follow-up or a longer time horizon could affect point estimates, although it is unlikely that the general conclusions would be altered considering the natural history of the clinical conditions under study [1,27].

The indirect costs are expressed as "productivity losses" according to the concept of opportunity cost [11,12]. They were computed following the capital human approach often applied in health economics, one that is recommended when adopting a societal perspective, even though this method may lead to overestimates and adopts general assumptions [11,25,28,29]. The methods for estimating indirect costs, however, are still a matter of debate [11,25,29,30]. Because of possible inequities in the labor market and other conceptual arguments, some have suggested a friction cost method instead [31,32]. Unfortunately, this alternate approach requires a large amount of detailed source information, something that is seldom available [25]. Regardless, we are ultimately interested most in incremental between-group differences from a clinical perspective, unless a systematic bias would exist favoring one or the other randomization arm, which is unlikely considering the clinical paths under study and the time horizon adopted.

The unit indirect costs were issued from general average wage rates per sex and age group for the time spent away from ADL, and from average daily wages for the time spent at the hospital (i.e., procedures, follow-up, and hospitalizations postprocedure). Hence, we did not use the real personal earnings of each patient enrolled in the RCT. We followed the recommendations to present both the quantity of lost time and the correspondent monetary value using general rate wages [11,25,29]. The measure of time lost was based on the recorded length of stay in hospital, in addition to the time spent away from ADL according to the patient, and a standardized assumed time necessary for a procedure (1 day for ERCP, half-day for an MRCP) and follow-up visits (half-day). Patients responded to a questionnaire estimating the time spent away from ADL with resultant limitations of recall bias and subjectivity. A more precise approach such as that recommended by Groover [33] that takes into consideration daily patient notes about each activity, time lost, and time motion approaches (e.g., to determine exact travel times) is difficult to apply in routine clinical medical research. The cost attributable to caregivers was not assessed, but may not be as applicable in this clinical context of what is most often an acute relapsing condition over a short time horizon. Intangible costs such as those attributable to pain or discomfort were not considered.

Conclusions

This cost analysis based on the randomized trial comparing the diagnostic strategies of MRCP-first and ERCP-first approaches in patients with suspected biliary obstruction due to bile duct stones suggests only a small difference in total per-patient costs. The Can$428 per-patient increment favors the ERCP-first

approach, and is principally attributable to procedural and hospitalization costs with little impact from indirect cost measurements; however, great variation in costs across upper and lower quartile estimates based on variations in resource use suggest that larger trials are warranted. These data mirror the effectiveness results that had been noted and were surprising, considering the relative safety of MRCP compared with the more invasive (but also therapeutic) ERCP. These findings also emphasize the need for true medical effectiveness trials measuring clinically relevant outcomes when comparing diagnostic strategies, regardless of how far downstream they may occur in the patient clinical management pathways.

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